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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,264	09/10/1999	CYNTHIA C. MORTON	10286/008001	3961

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	27

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,264	MORTON ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *8-17 and 19-28* is/are withdrawn from consideration.

5)☒ Claim(s) *29* is/are allowed.

6)☒ Claim(s) *1,2,18,30,32 and 33* is/are rejected.

7)☒ Claim(s) *3-7 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *25,26* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed September 9, 2002 (Paper No. 20) in response to the Office Action of February 27, 2002 is acknowledged and has been entered. Claims 1-33 are pending and claims 1-7, 18, 29-33 are currently being examined. Claims 8-17, and 19-28 have previously been withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Two interviews were conducted with applicant's representative Laurie Butler Lawrence on November 7th and 22nd, 2002 (Paper Nos. 25 and 26).

In the first interview (paper No. 26) allowable subject matter was indicated and a request for an examiners amendment was made. The claims drawn to the non-elected invention were to be canceled and references to the allelic variants were to be deleted. Claim 30 was to include the limitation "and which binds fibrillar collagen" after the last sequence identifier. In claim 31 the first reference to "comprising" was to be deleted. None of these discussed changes have been made to the claims.

In the subsequent interview (Paper No. 26) applicant was notified of art of interest WO 99/14328, which was supplied in the last Office Action (Paper No. 20). Figures 81 and 82 are of particular interest as figure 82 has 100% sequence identity with SEQ ID NO 2 and figure 81 has 99.9% sequence identity with SEQ ID NO: 3 (one nucleotide difference in a wobble base). Applicant was notified with this interview that SEQ ID NO:1, SEQ ID NO: 6 and SEQ ID: 7 would be allowable if limited to the sequence. Applicant was advised that there may be a

possibility of an obvious type double patenting (ODP) rejection at a later date if sequences are issued, of specific concern was SEQ ID NO:1. To avoid potential future ODP rejection with SEQ ID NO 6 and 7 applicant was given the opportunity to amend claim 1 to have 95% sequence identity. An agreement could not be reached; therefore, the instant office action is issued.

The rejection of claims 1 **is withdrawn** because the claim has been amended to include the function of binding of fibrillar collagen.

The rejection of claim 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reasons of record. Applicant's urge that the specification sufficiently describes how to make homology determinations and how to make conservative amino acid substitutions. The ability to make such changes fails to persuade that these changes will necessarily result in a molecule that has the same function. To meet the functional requirement, the function must be measurable by the ordinary artisan. For example measuring the interaction of a binding activity or substrate turnover. Amending the claim to include functionality will obviate the rejection. The rejection is maintained for not being supported by a written description.

The rejection of claims 1 **is withdrawn** because the claim has been amended to include the function of binding of fibrillar collagen.

The rejections of claim 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record. Applicant's urge that the specification describes how to make homology determinations and how to make conservative amino acid substitutions. The ability to make such changes fails to persuade that these changes will necessarily result in a molecule that has the same function. To meet the functional requirement, the function must be measurable by the ordinary artisan. For example measuring the interaction of a binding activity or substrate turnover. Amending the claim to include functionality will obviate the rejection. The rejection is maintained.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicant's amendment indicating that the molecule will bind fibrillar collagen.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicant's amendment.

The rejection of claims 29 and 31 is withdrawn in view of applicants arguments.

The rejection of claims 1, 2, 18, 30, 32 and 33 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reason of record. Applicant's advocate that the "Guidelines" indicate that a written description requirement for an isolated nucleic acid molecule can be satisfied with the disclosure of a single species. Applicant's arguments fail to persuade the office, the guidelines (Fed. Register, Vol. 66, No. 4, January 5, 2001) indicate where a genus is claimed sufficient written description may be provided by a representative number of species that have been reduced to practice. Relevant, identifying characteristics, i.e., structure or other physical and/or biochemical properties, by functional characteristics coupled with a known or disclosed correlation between function structure, or by a combination of identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. The guidelines go on to say that there are instances where a single disclosed species may be adequate to describe the genus. Because, the claims are drawn to isolated nucleic acid molecules which according to the specification (see page 16) includes cDNA and genomic DNA as well as allelic variants, the disclosure of the open reading frames (from human and mouse) is not sufficient to identify the genus, which included genomic DNA and allelic variants. The nucleic acid sequence similarity between human and mouse is 89% in the area covering the open reading frame. The areas outside of the open reading frame are not identified structurally in the specification. The specification discloses isolated cDNA sequence, SEQ ID Nos : 1 and 6, which encodes a predictive polypeptide sequence, SEQ ID NOs. 2 and 7. Absent evidence to the contrary, each of the SEQ ID NOS elected for examination is deemed to

be cDNA. The claims, as written, however, encompass polynucleotides which vary substantially in length and in nucleotide composition, the genes also include undescribed 5' and 3' regulatory elements. The broadly claimed genus additionally encompasses genes as well as genes incorporating only portions of the disclosed sequence. The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus of genomic DNA or allelic varients, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed. The rejection is maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 18 is provisionally rejected under the judicially created doctrine of double patenting over claims 17-21 of copending Application No. 09/579288. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The office acknowledges that applicants will provide a terminal disclaimer when either the present application of the co-pending application are indicated to be allowable.

The objection of claims 3-7 **is maintained**, claim 4 has been added in view of applicants amendment to the claim. The applicant is reminded that amending the claims to incorporate the limitations of claims 3-7 will not necessarily result in an allowable base claim.

New Objection:

Claim 31 is objected to because of the following informalities: The claim reads "...nucleic acid molecule comprising which encodes a fragment of a polypeptide comprising...". For readability the first "comprising" in the claim should be deleted. Appropriate correction is required.

Conclusion

Claim 29 is allowable.

Claims 3-7 and 31 are objected to.

Claims 1, 2, 18, 30, 32 and 33 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600